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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,899	BUNICK ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8,9 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8,9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 9-18-08 is acknowledged.

Claims 1-3, 5, 8-9, 11-13 are pending in the instant application.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5, 8-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 B1 to Boissonneault et al ('050) in view of US 3,619,292 to Brouillard ('292) OR US 6,667,050 B1 to Boissonneault et al ('050) and US 4,684,534 to Valentine ('534) in view of US 3,619,292 to Brouillard ('292).

3. '050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050 contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate. The compositions of '050 do not necessarily require fat, non-saccharide water soluble binder or aspartame (claims 1, 8 and 11) (examples 3 and 6) and thus meet the claimed limitation. The examples of '050 teach the claimed disintegrants and lubricants (see examples) and other auxiliary ingredients of claim 12 (examples and col. 5-6).

4. '050 teach dextrose but not dextrose monohydrate and the claimed particle sizes.

5. '292 teach forming a free-flowing tablet containing a binder or a binder-filler, which is a sugar granule. The sugar granule comprises aggregates of cohered

microcrystals of dextrose (abstract and col. 1, L 1- 20). According to '292 dextrose hydrate provides more advantages when employed in direct compression than in wet granulation or dry granulation because it produces a cooling effect when dissolved in the mouth, which is highly desirable for a tableted food or a pharmaceutical and can also enhance the flavor in the tablet (col. 2, L 10-35), particularly chewable drug tablets (col. 5, KL 55-58).

6. Valentine '534 teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 4, L 29-35 & col. 9, lines 20-42) and particulate active agent having a particle size of about 50 microns (col. 4). '534 teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Valentine clearly states that the tablet is prepared by direct compression (col. 1, L 57-63).

7. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates or granules such as dextrose or dextrose monohydrate (of Valentine '534 or '292) in the composition of '050 for preparing directly compressed tablets because Valentine '534 teach that dextrose and dextrose monohydrate are equally effective for compressibility, the tablets are highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. Further '292

also teach that dextrose monohydrate particles disintegrate very quickly in the mouth and enhance the flavor of the tablet. With respect to the ratio of dextrose monohydrate and sucralose, the example compositions of '050 contain high amounts of dextrose compared to the sweeteners such as sucralose and aspartame. In this regard, applicants have not established any unexpected advantage with the claimed ratio and accordingly choosing the appropriate amounts of binders and sweeteners to achieve the desired effect would have been within the scope of a skilled artisan.

Response to Arguments

1. Applicant's arguments filed 9-18-08 have been fully considered but they are not persuasive.

2. Applicants' argue that instant claims have been amended to recite the specific range of sucralose i.e., 0.5% to 5% and a ratio of dextrose monohydrate to sucralose of 25:1. It is argued that the cited references fail to teach the above limitations. It is argued that Boissonneault in example 11 teaches 0.017% sucralose and 58.3% dextrose and that even if one were to substitute dextrose monohydrate for dextrose one would not arrive at the claimed range. Applicants' arguments are not persuasive because the amount of dextrose of Boissonneault i.e., 58.3% is within the claimed range and the rejection above provides the requisite motivation to substitute dextrose monohydrate for dextrose, the rationale of which has not been argued. With respect to the amount of sucralose, it is agreed that Boissonneault teaches sucralose as a sweetener. A skilled artisan would have been able to adjust the amount of a sweetener in a tablet composition depending on the level of sweetness desired. Generally, differences in

concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The prior art teaches dextrose (monohydrate) and sucralose for their binder and sweetener effect and in the absence of any unexpected advantage with the claimed ratio of the two components, it would have been within the scope of a skilled artisan to optimize the individual amounts of the components with an expectation to achieve the art recognized effect. Therefore the arguments regarding the patentability of instant claims over Boissonneault, Brouillard et al and Valentine are not found persuasive.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
January 4, 2009